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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,587	02/12/2001	Anders Hjelholt Pedersen	0212us310	9481

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MAXYGEN, INC.
INTELLECTUAL PROPERTY DEPARTMENT
515 GALVESTON DRIVE
RED WOOD CITY, CA 94063

EXAMINER

TELLER, ROY R

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 08/12/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/782,587

Applicant(s)

PEDERSEN ET AL.

Examiner

Roy Teller

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1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68-70,85-89,91-95 and 103-105 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 68-70,85-89,91-95 and 103-105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12. 6) ☐ Other: _____

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DETAILED ACTION

This office action is in response to Paper No: 15A, received 6/19/03, in which applicant cancelled claims 1-67 and added new claims 68-116. Applicant has elected group I, claims 69-92 and 103-105 with traverse. Applicant's traversal points out that a search of group II, claims 93-95, would be co-extensive with a search of the group I conjugate, since the conjugate comprises the peptide. The examiner finds this argument persuasive, groups I and II are rejoined. Applicant elected species T106N with traverse. Applicant's traversal points out that MPEP 803.04 entitles the applicant to elect ten nucleotide sequences. The examiner does not find this argument persuasive, as it is amino acid sequences that are being searched.

The requirement is still deemed proper and is therefore made FINAL.

Claims 68-70, 85-89, 91-95, and 103-105 are pending and will be examined to the extent that they read on SEQ ID NO: 1.

Information Disclosure Statement

The information disclosure statement files 7/8/02 (Paper No: 12) is acknowledged. A signed copy is attached hereto.

Claim Objections

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The specification and claims are objected to for failing to adhere to the requirements of the sequence rules. Applicant must append SEQ ID NO's to all mentions of specific sequences in the specification and the claims. See 37 CFR 1.821(d).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 68 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

A review of the language of the claim indicates that these claims are drawn to a genus,

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i.e., the genus of conjugates of factor VII (FVII) and factor VIIa (FVIIa) which differs from SEQ ID NO:1 in 1-15 amino acid residues and comprises an introduced *in vivo* N-glycosylation site relative to SEQ ID NO:1, wherein the introduced *in vivo* N-glycosylation site comprises the substitution: T106N; and a sugar moiety covalently attached to the introduced *in vivo* N-glycosylation site.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention".

There is a single species of the claimed genus disclosed that is within the scope of the claimed genus, i.e. SEQ ID NO:1. The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described. There

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is substantial variability among the species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises the genus of conjugates of factor VII (FVII) and factor VIIa (FVIIa) which differs from SEQ ID NO:1 in 1-15 amino acid residues and comprises an introduced *in vivo* N-glycosylation site relative to SEQ ID NO:1, wherein the introduced *in vivo* N-glycosylation site comprises the substitution: T106N; and a sugar moiety covalently attached to the introduced *in vivo* N-glycosylation site. The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed” (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

All other claims depend directly or indirectly from the rejected claim and are, therefore, also rejected under 35 USC 112, first paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 68-70, 85-89, 91-95, and 103-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berkner, SPN 5,816,374.

The claimed invention is drawn to conjugates of factor VII (FVII) and factor VIIa (FVIIa) which differs from SEQ ID NO:1 in 1-15 amino acid residues and comprises an introduced *in vivo* N-glycosylation site relative to SEQ ID NO:1, wherein the introduced *in vivo* N-glycosylation site comprises the substitution: T106N; and a sugar moiety covalently attached to the introduced *in vivo* N-glycosylation site.

Berkner teaches pharmaceutical compositions of modified factor VII that are used to treat a variety of coagulation-related disorders, see abstract. Berkner discloses SEQ ID NO:2, which has a 99.1% query match with SEQ ID NO:1 of the instant application, GenCore version 5.1.6, page 5, result 7.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the modified factor VII of Berkner, because Berkner teaches the use of the modified factor VII in a variety of coagulation-related disorders.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RT
1654
8/11/03

RT

A handwritten signature in black ink, appearing to be 'C. R. Tate', enclosed within a large, loopy oval shape.

CHRISTOPHER R. TATE
PRIMARY EXAMINER